DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

06-PHI-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 20, 2006

Richard J. Fugo, M.D., Ph.D.
President & CEO
Medisurg Research & Management Corporation
100 West Fornance Street
Norristown, PA 19401

Dear Dr. Fugo:

During an inspection of your establishment located in Norristown, Pennsylvania, on April 25, 2006 through May 4, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer of the Fugo Blade System, a battery operated, electrosurgical cutting apparatus used for capsulotomy, glaucoma and peripheral iridotomy. Electrosurgical cutting apparatus are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

The above-stated inspection revealed that your devices are adulterated under section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices, which are set forth in the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for validating the manufacturing process, and failure to adequately document process validation [21 CFR 820.75]. Specifically, there was no documentation to confirm post-sterilization package integrity testing for your disposable cutting tips, accessories to the Fugo Blade System, as part of the requirement of the ethylene oxide sterilization protocol.

We acknowledge receipt of your letter dated May 31, 2006, written in response to the FDA-483. Upon review of your letter, we have determined that your choice of 100% visual examination is not sufficient to ensure post-sterilization package integrity. We believe that you need to develop a measurable test that demonstrates that package integrity has been maintained after sterilization.

We have reviewed your responses to Observations 2-10 of the Form FDA-483. Your responses to these Observations appear to be adequate. However, a follow-up inspection will be required to assure that the corrections are adequate.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act, and FDA regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System Regulation deficiencies are reasonably related, will be cleared until the violations have been corrected. Also, no requests for the Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct the violation addressed in this letter. Failure to promptly correct this violation may result in regulatory action being initiated without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Richard C. Cherry, Compliance Officer, at U.S. Customhouse, Room 900, 200 Chestnut Street, Philadelphia, PA 19106.

Sincerely,

Thomas D. Gardine
District Director
Philadelphia District Office

cc: Pennsylvania State Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104
Attention: Robert E. Bastian, Director
Division of Primary Care and
Home Health Services